Agency:	**107 Health Care Authority**
Decision Package Code/Title:	**ML2-AD Improve Efficacy of Hep C Treatment**
Budget Period:	**2015-17 Biennial Submittal**
Budget Level:	**ML2 – Maintenance Level 2**

Recommendation Summary Text

The Health Care Authority (HCA) requests $373,910,000 ($90,200,000 GF-State) in the 2015-17 biennium to support a new oral hepatitis C treatment. New oral treatments were recently approved by the federal Food and Drug Administration (FDA) that greatly improves the success rate of hepatitis C treatment and the quality of life for patients receiving treatment. An estimated 4,301 Medicaid clients will receive this treatment during the biennium. Based on available research data, estimates are that up to 90 percent of those treated could have a sustained viral response (SVR) to treatment.

Package Description

At the end of calendar year 2013, two new oral treatments for hepatitis C were approved by the FDA, Sovaldi (sofosbuvir) and Olysio (simeprivir). These treatments were the first in a new generation of highly effective drugs known as "Direct Acting Antivirals" (DAA) to be approved by FDA.

At this time, Sovaldi in particular promises to greatly improve treatment efficacy and reduce the standard length of treatment. Although the arrival of Solvadi will help cure thousands, it will be at a tremendous cost. One pill of Sovaldi is priced at $1,000. The typical hepatitis C patient will be on a 12 week regimen, meaning Sovaldi costs alone will be $84,000 per patient. Although drugs can be purchased at prices below $1,000 – in part due to the federal drug rebates available under the Medicaid program – the cost will still be very high. There is limited ability to obtain up-front discounts through 340B pricing of these drugs, and some risk in relying on estimates of either 340B pricing or net of rebate calculations.[1]

It is expected that the FDA will approve additional DAAs in late 2014 and early 2015. Available data suggests – that especially when used in combination – these drugs will be highly effective in the treatment of hepatitis C. The costs of newer agents individually and in combination have not yet been determined. However, it is expected that Sovaldi will remain the cornerstone of many regimens until at least 2016 and 2017.

If left untreated, hepatitis C can cause severe liver damage and scarring (fibrosis), cirrhosis, liver cancer (hepatocellular carcinoma), and ultimately death. However, many patients will not progress to the advanced stages of disease and will not experience these unfortunate outcomes. Current hepatitis C treatment policies of many health plans and payers (including the Washington State Public Employee Benefits (PEB) program and Medicaid health plans) limit treatment with Sovaldi to patients with more advanced levels of fibrosis because these patients are most likely to progress to cirrhosis and hepatocellular carcinoma.

[1] There are a limited number of 340B providers qualified to prescribe hepatitis drugs. The value of 340B up-front discounts and Medicaid drug rebates are roughly comparable; and both are subject to change without notice.

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An estimated 4,301 Medicaid clients will receive this treatment during the biennium. The HCA requests $373,910,000 ($90,200,000 GF-State) in the 2015-17 biennium to support for the new oral hepatitis C treatment.

Questions related to this request should be directed to Christy Vaughn at (360) 725-0468 or at Christy.vaughn@hca.wa.gov.

Fiscal Detail/Objects of Expenditure

	FY 2016	FY 2017	Total
1. Operating Expenditures:			
Fund 001-1 GF-State	$ 64,130,000	$ 26,070,000	$ 90,200,000
Fund 001-C GF-Federal Medicaid Title XIX	$201,690,000	$ 82,020,000	$283,710,000
Total	**$265,820,000**	**$108,090,000**	**$373,910,000**

	FY 2016	FY 2017	Total
2. Staffing:			
Total FTEs	-	-	-

	FY 2016	FY 2017	Total
3. Objects of Expenditure:			
A - Salaries And Wages	$ -	$ -	$ -
B - Employee Benefits	$ -	$ -	$ -
C - Personal Service Contracts	$ -	$ -	$ -
E - Goods And Services	$ -	$ -	$ -
G - Travel	$ -	$ -	$ -
J - Capital Outlays	$ -	$ -	$ -
N - Grants, Benefits & Client Services	$265,820,000	$108,090,000	$373,910,000
Other (specify) -	$ -	$ -	$ -
Total	**$265,820,000**	**$108,090,000**	**$373,910,000**

	FY 2016	FY 2017	Total
4. Revenue:			
Fund 001-C GF-Federal Medicaid Title XIX	$201,690,000	$ 82,020,000	$283,710,000
Total	**$201,690,000**	**$ 82,020,000**	**$283,710,000**

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Narrative Justification and Impact Statement

What specific performance outcomes does the agency expect?

Over the course of the biennium, it is estimated that 4,301 clients with chronic hepatitis C will undergo treatment. Based on available research data, estimates are that up to 90 percent of clients could have a sustained viral response (SVR) to treatment. Those with an SVR would be far less likely to progress to advanced liver disease (i.e. cirrhosis or liver cancer) or experience other complications associated with chronic hepatitis C infection, including death.

An estimated 3,871 Medicaid clients will achieve a sustained viral response during the biennium.

Performance Measure Detail

Activity Inventory

H005 HCA National Health Reform

H011 HCA All Other Clients – Fee for Service – Mandatory Services

Is this decision package essential to implement a strategy identified in the agency's strategic plan?

The HCA's strategic plan emphasizes the triple aim: better population health, more effective care, and lower costs. Effective treatment of hepatitis C will improve population health. While it is unclear whether hepatitis C is cost-saving in the long run (i.e. over 20-25 years), treatment of those with more severe liver fibrosis is cost-effective[2].

Does this decision package provide essential support to one or more of the Governor's Results Washington priorities?

This strategy supports Goal 4.1.2: Decrease the proportion of adults reporting fair or poor health from 15 percent to 14 percent by 2014. Patients with chronic hepatitis C who develop cirrhosis and its complications are likely to report overall poor health status. By treating chronic hepatitis C, patients will avoid adverse health consequences, and be more likely to report better health status.

What are the other important connections or impacts related to this proposal?

Because hepatitis C is undiagnosed among anywhere from 25-50 percent of those persons affected, and because it can often result in chronic disease, there is a large public health push to identify persons with infection. This is a message shared by the federal Centers for Disease Control (CDC), local health departments, and hepatitis advocacy groups. In addition, because the new therapies are so effective, there is the potential to completely eradicate the disease. As such, all of the aforementioned groups are advocating for the treatment of all patients with hepatitis C. The medical community, in particular providers caring for patients with hepatitis C, are also advocating for the treatment of their patients who have progressed with their disease now that better tolerated and more effective drugs are available.

[2] Ollendorf, Daniel A., Jeffrey A. Tice, and Steven D. Pearson. "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir for Chronic Hepatitis C Virus Infection." *JAMA internal medicine* (2014)

From a legal standpoint, state Medicaid programs are required to cover FDA approved drugs for which the manufacturer has negotiated a federal rebate. Such is the case for Sovaldi. However, Washington State Medicaid can impose reasonable medical necessity criteria in making coverage determinations.

What alternatives were explored by the agency, and why was this alternative chosen?
The only viable alternative to this strategy is to treat people with more severe disease: those patients who by definition have cirrhosis, liver cancer or are in need of a liver transplant. Not only would this be extremely unpopular among all stakeholder groups and a short-sided risk management strategy, it would be objectionable from a medical ethical standpoint.

What are the consequences of adopting this package?
Adoption of this package would allow for treatment of those patients most at risk for progression of their chronic liver disease, with an overall improvement in individual clinical outcomes and population health. The stakeholders mentioned above – public health, advocacy groups and the provider community – will voice concern that there are any restrictions placed on treatment, but they will be more supportive of this option than waiting until more advanced disease has occurred.

What is the relationship, if any, to the state capital budget?
None

What changes would be required to existing statutes, rules, or contracts, in to implement the change?
None

Expenditure and Revenue Calculations and Assumptions

Revenue Calculations and Assumptions:
The HCA assumes that the Medicaid services funded by this proposal will be eligible for federal matching funds. The exact amount of federal funds depends on the mix of newly eligible adults and non-newly eligible clients receiving treatment.

Payment of treatment for non-newly eligible clients would receive the federal medical assistance percentage (FMAP). There are two federal payment percentages that impact the newly eligible federal fund match rate: the newly eligible FMAP rate and the presumptive SSI federal match rate. Presumptive SSI eligible clients make up part of the overall newly eligible group and receive a unique federal match rate. The federal matching fund rates used to estimate federal funds are provided in the table below.

Federal Matching Funds Rate Assumption

	Fiscal Year 2016	Fiscal Year 2017
Non-newly eligible FMAP	50.08%	50.10%
Newly eligible combined	99.18%	96.94%
Presumptive SSI	82.53%	85.53%
Newly eligible FMAP	100%	97.5%

Expenditure Calculations and Assumptions:
The first step in determining the fiscal impact of new hepatitis C treatment is to estimate the number of Medicaid clients with hepatitis C. Prevalence rates of hepatitis C were estimated by age/gender groups. Two approaches were used in calculating these rates; one for newly eligible adults, and another for non-newly eligible clients:

1. Newly eligible adult prevalence rates were derived from statistics published by the National Health and Nutrition Examination Survey (NHANES).

2. Non-newly eligible prevalence rates were derived from ProviderOne claims data. An analysis of the prevalence rate of hepatitis C was conducted for clients just prior to open enrollment in September 2013. This time period was selected to avoid any influence of the Affordable Care Act (ACA), and to isolate the prevalence rate among non-newly eligible clients.

Separate prevalence rates were computed because there is ample historical data for the non-newly eligible population for which to base assumptions. However, many newly eligible clients are new to Medicaid and there is little data to base an inference of hepatitis C prevalence. In addition to data limitations, evidence suggests that there are many hepatitis C positive non-newly eligible clients who are on disability and eligible as Categorically Needy disabled adults. This means that there are likely clients who are enrolled in Medicaid because they have chronic hepatitis C, or have inflictions that correlate with having hepatitis C. These prevalence rates exclude Medicaid dual eligible clients and clients with a scope of service that doesn't cover hepatitis C treatment.

Once the estimated count of clients with chronic infection is established, the count estimate is further refined to include only those that would qualify for treatment. The treatment qualifying event occurs when F3 fibrosis is detected. It is estimated that 33 percent of current chronically infected clients have stage F3 or greater disease[3].

There are multiple types, or genotypes, of hepatitis C. Different genotypes of hepatitis C respond best to different treatment regimens, so an estimated distribution of genotypes is applied to the

[3] Poynard, Thierry, Pierre Bedossa, and Pierre Opolon. "Natural history of liver fibrosis progression in patients with chronic hepatitis C." *The Lancet* 349.9055 (1997): 825-832.

number of clients with F3 or greater fibrosis. Looking again to literature as a guide, an average distribution of hepatitis C genotypes is assumed.

Further, it is assumed that only a portion of clients with F3 fibrosis are aware that they have hepatitis C. An estimated 75 percent of clients are aware of their infection during calendar years 2014 and 2015. This percentage is estimated to increase to 90 percent in calendar year 2016 and beyond due to increased awareness of hepatitis C and a push to screen more patients.

Medicaid drug acquisition prices are based on actual experience since Solvaldi based treatment has already begun. An analysis of historical hepatitis C drug purchasing patterns revealed that about 12 percent of pharmaceuticals for hepatitis C treatment were purchased through a participating 340B provider. It is assumed that this pattern will persist and that the remaining 88 percent of pharmaceuticals would be purchased at the payment rate and will be partially offset by a drug rebate.

A total cost is computed by applying the cost of treating each hepatitis C genotype against the estimated number of clients with F3 fibrosis per genotype.

Cost-offsets

To estimate future avoided costs as a result of more effective hepatitis C treatment, a cost-offset model was developed. The cost-offset model uses a cohort approach to identify non-dual adult CN Blind/Disabled clients for which at least one claim exists in calendar year 2006 with a hepatitis C diagnosis code. Any client identified with an advanced liver disease in calendar year 2006 is excluded from the cohort.

Two sub-populations are identified and analyzed:

1. Chronic condition sub-population: Clients who develop an advanced liver disease between calendar years 2007 and 2011 inclusive.
2. Reference sub-population: Clients who do not experience an advanced liver condition over calendar years 2007 to 2011.

Based on the above sub-populations, trended per-member per month costs are calculated into fiscal year 2017 based on rough historical cost trends from calendar years 2007 to 2010. This analysis accounts for attrition off of the sub-population due to: (1) mortality, (2) dual eligibility status, (3) loss of Medicaid coverage. Also, any member months and costs in which capitation payments are made for the client are eliminated.

An assumed adherence and effectiveness rates for the chronic condition sub-population are applied and assumed that those who are treated effectively will have per-member per month experiences similar to the reference sub-population.

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Which costs, savings, and functions are one-time? Which are ongoing? What are the budget impacts in future biennia?

Distinction between one-time and ongoing costs:

Costs are expected to be ongoing. There will be a surge in treatment as clients who have F3 or greater fibrosis are treated, creating higher costs in the medium term.

Budget impacts in future biennia:

Hepatitis C treatment will continue to be offered to clients with stage F3 fibrosis. Clients will continue to progress to F3 fibrosis and will require treatment.

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